Solventum MedTech OEM
Product clinical data summary
Product Name: Solventum™ Medical Tape 1527/1527MS
Effective: July 2021

The adhesive used in Medical Tape 1527/1527MS, as part of a different construction, has been subjected to the following preclinical biocompatibility evaluations per ISO 10993 standards under FDA GLP Regulations (21 CFR Part 58):

Cytotoxicity Study Using the ISO Elution Method
The test article was evaluated for potential cytotoxic effects using an *in vitro* mammalian cell culture test.This study was conducted following the guidelines of ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (1X MEM) at 37°C for 24 hours. The negative control, reagent control, and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO^2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

CLIN-RPT-FINAL-INV-US-05-629333

ISO Skin Irritation Study in Rabbits
The test article was evaluated for primary skin irritation in rabbits. This study was conducted in accordance with the guidelines of ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization. Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for a minimum of 23 hours and a maximum of 24 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application. There was no to well-defined erythema and no to very slight edema observed on the skin of the animals treated with the test article. The Primary Irritation Index for the test article was calculated to be 1.0/8.0. The response of the test article was categorized as slight.

CLIN-RPT-FINAL-INV-US-05-629329

ISO Guinea Pig Maximization Sensitization Test
The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig. This study was conducted based on the requirements of ISO 10993-10, Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization. The test article was occlusively patched to the intact skin of ten animals for 6 hours (± 30 minutes), three times a week, over a 3 week period. The control article was similarly patched to five animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test article and the control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

CLIN-RPT-FINAL-INV-US-05-629312

It is the responsibility of our customers to determine final suitability of our products for their application. Final testing of a converted device made with this material is the responsibility of the customer.

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